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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,752		Johannes Jacobus Voorberg	294-86	5298

7590 09/10/2003

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EXAMINER
HADDAD, MAHER M

ART UNIT	PAPER NUMBER
1644	12

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,752	VOORBERG ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/07/01, 10/29/02 and 11/25/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *17-84* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1.Applicant's amendments, filed on 5/07/01, 10/29/02 and 11/25/02 (Paper No. 5, 10 and 11, respectively), is acknowledged.

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented.

Misnumbered claims 17-79 have been renumbered as claims 24-86, respectively according to 37 CFR 1.126.

3. The Examiner considered the polynucleotide of claim 61, which depends from claim 60, as intended to read on a polypeptide.

Election/Restrictions

4. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 17-18, 20, 60-81 and 85-86, drawn to a polypeptide capable of specific binding to factor VIII and interference with the activity of factor VIII inhibitors, which polypeptide comprises the variable part of the heavy chain of a human antibody with factor VIII specificity or a part thereof which at least includes the CDR3 region and a pharmaceutical composition thereof and a method of producing the a recombinant polypeptide antibody.

II. Claim 81, drawn to a pharmaceutical composition for the treatment of factor VIII inhibition comprising a polypeptide that specifically binds an antibody specific for factor VIII.

III. Claims 81-82, drawn to a pharmaceutical composition for the treatment of factor VIII inhibition comprising a polypeptide that specifically binds an antibody specific for factor VIII and further comprising factor VIII or a compound with factor VIII activity.

IV. Claims 20-21 and 81-82, drawn to a pharmaceutical composition for the treatment of factor VIII inhibition comprising a polypeptide that specifically binds factor VIII and further comprising factor VIII or a compound with factor VIII activity.

V. Claims 19 and 24-57, drawn to a polynucleotide in substantially isolated form, coding for a polypeptide capable of specific binding to factor VIII and interference with the activity of factor VIII inhibitors, which polypeptide comprises the variable part of the heavy chain of a human antibody with factor VIII specificity or a part thereof which at least includes the CDR3 region and a pharmaceutical composition thereof and a kit thereof.

VI. Claims 22 and 83, drawn to a method of treatment of factor VIII inhibition in a human individual comprising administering a polypeptide capable of specific binding to factor VIII and interference with the activity of factor VIII inhibitors, which polypeptide comprises the variable part of the heavy chain of a human antibody with factor VIII specificity or a part thereof which at least includes the CDR3 region and a pharmaceutical composition thereof.

VII. Claims 83, drawn to a method of treatment of factor VIII inhibition in a human individual comprising administering a polypeptide capable of binding an antibody specific to factor VIII.

VIII. Claims 83-84, drawn to a method of treatment of factor VIII inhibition in a human individual comprising administering a polypeptide that specifically binds an antibody specific for factor VIII and further comprising factor VIII or a compound with factor VIII activity.

IX. Claims 23 and 83-84, drawn to a method of treatment of factor VIII inhibition in a human individual comprising administering comprising a polypeptide that specifically binds factor VIII and further comprising factor VIII or a compound with factor VIII activity.

X. Claims 58-59, drawn to a method for detecting a nucleic acid encoding a human antibody specific for factor VIII, comprising providing a sample containing nucleic acids for testing and contacting the sample with a polynucleotide probe.

5. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of claim 60 was found to have no special technical feature that defined the contribution over the prior art of Gilles et al (Blood. 82(8):2452-6241, 1993) (see entire document) (see IDS).

Gilles et al teaches different anti-Factor VIII antibodies of hemophiliac A patients (see abstract and table I page 2462 in particular). The referenced antibodies comprises an amino acid sequence from a complementarity-determining region of a human antibody specific for factor VIII as recited in claim 60(a) because the antibody is derived for hemophiliac A patients (human). The recitation of "comprises an amino acid sequence from a complementarity-determining region of a human antibody specific for factor VIII" is inherent properties of the referenced antibodies.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

6. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If anyone of Groups I, III, IV or V is elected, applicant is required to elect a polypeptide capable of specific binding to Factor VIII, wherein the heavy chain variable region is derived from one specific 1) DP-10, 2) DP-14, 3) DP-15, 4) DP-31, 5) DP-47, 6) DP-49 or 7) DP-77) encoded by a polynucleotide comprising as one specific VH-gene segment of 1) DP-10, 2) DP-14, 3) DP-15, 4) DP-31, 5) DP-47, 6) DP-49 or 7) DP-77. These are distinct species because their structures and modes of action are different; a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad, whose telephone number is (703) 306-3472. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
August 28, 2003

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600